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10/517,220

12/07/2004

Luppo Edens

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23117 7590 12/02/2009  
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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

12/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,220	<b>Applicant(s)</b> EDENS ET AL.	
	<b>Examiner</b> Richard G. Hutson	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-47 is/are pending in the application.
- 4a) Of the above claim(s) 23, 24, 27, 29-33, 38, 41, 44 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-22, 25, 26, 28, 34, 35-37, 39, 40, 42, 43, 45, 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/16/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment of the specification and claim 17-25, 32-34 and 39-47, in the paper of 7/30/2009, is acknowledged. Claims 17-47 are pending and at issue.

Claims 23, 24, 27, 29-33, 38, 41, 44, 47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of an information disclosure statement on 4/16/2009, is acknowledged. Those references considered have been initialed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 1652

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-19 , 25, 26, 28, 34, 35-37, 39, 40, 42, 43, 45, 46, are rejected under 35 U.S.C. 102(b) as being anticipated by Nagodawithana and Reed (eds.), *Enzymes in Food Processing*, 3<sup>rd</sup> Edition, Academic Press, Inc. San Diego, Chapter 16, pp 448-449, 1993, See IDS).

This rejection was stated in the previous office action as it applied to previous claims 17-19 , 25, 26, 28, 34, 35-37, 39, 40, 42, 43, 45, 46. In response to the rejection applicants have amended claims 17-25, 32-34 and 39-47 and traverse the rejection as it applies to the newly amended claims.

As previously stated, Nagodawithana and Reed teach a method to prevent or reduce haze in a beverage, which method comprises adding a proline-specific endoprotease, as defined by applicants specification at page 3, lines 15-22, to include any endoprotease that cuts proteins or peptides near or at places where the protein or peptide contains a prolyl-residue in its chain, to the beverage, in this case beer. Nagodawithana and Reed teach methods of reducing haze in a beverage comprising the addition of bromelin, papain and pepsin to a beverage.

Applicants traverse this rejection on the basis that applicants submit that in contrast to applicants claimed invention, Nagodawithana discloses that haze in beer results from interactions between proteins and polyphenolic procyanidins and that the enzymes Bromelin, papain, and pepsin disclosed by Nagodawithan are not prolyl-specific endo-proteases that cut a protein or peptide at places where the protein or

Art Unit: 1652

peptide contains a prolyl residue. Thus, applicants submit that the cited document does not teach Applicants' claimed method for the prevention or reduction of haze in a beverage.

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however, is found nonpersuasive for the reasons previously made of record and repeated herein. As stated previously, applicants specifications at page 3, lines 15-22 defines a prolyl-specific endoprotease as any endoprotease that cuts proteins or peptides near or at places where the protein or peptide contains a prolyl-residue in its chain, thus as the enzymes taught by Nagodawithana, cuts proteins or peptides near or at places where the protein or peptide contains a prolyl-residue in its chain, they are considered prolyl-specific endoproteases. These enzymes further cut a protein or peptide at places where the protein or peptide contains a prolyl residue.

Thus claims 1-9, 13, 14, 16, 31, 32, 40, 42 and 44 continue to be anticipated by Nagodawithana and Reed.

Claims 17, 19, 25, 28, 34, 39, 42 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Shetty et al. (U.S. 4,532,213, published 7/30/1985)

This rejection was stated in the previous office action as it applied to previous claims 17, 19, 25, 28, 34, 39, 42 and 45. In response to the rejection applicants have amended claims 17-25, 32-34 and 39-47 and traverse the rejection as it applies to the newly amended claims.

Art Unit: 1652

As previously stated, Shetty et al. teach methods of recovery of acid fungal proteases for their use in food, brewing and photographic industries, which comprise which comprises adding the fungus, *Aspergillus niger*, comprising a proline-specific endoprotease and an auxiliary enzyme to an aqueous medium (beverage) wherein the addition of said auxiliary enzyme results in further prevention or reduction of haze than is achievable with the proline-specific endoprotease alone. Applicant's specification at page 3, lines 9-13 are recognized in the recitation:

"In the framework of this invention the term "beverage" includes beverages in all stages of their preparation. Thus, a beverage is not only a beverage ready for consumption but also any composition used to prepare the beverage. For example, wort as used in beer preparation is encompassed by the term "beverage" as used herein. Also, the addition of a prolyl-specific endoprotease during the preparation of a beverage to compositions that are not or not entirely liquid is intended to fall within the method according to the invention. A prolyl-specific endoprotease added to a mash at the start of beer brewing is an example of such a composition. "

While it is admitted that Shetty et al. do not add the two different enzymes separately after their isolation or purification, Shetty et al. do add the two enzymes inherently by the addition of the culture of *Aspergillus niger* to the medium.

Applicants traverse this rejection on the basis that it was alleged in the Office Action that Shetty teaches adding the fungus *A. niger* comprising a proline-specific endoprotease and an auxiliary enzyme to an aqueous medium and Applicants submit that this is incorrect. Applicants submit that Shetty merely refers to an acid fungal protease and that no endoprotease is ever mentioned in Shetty, much less a prolyl-specific endoprotease.

Applicants further submit that Shetty discloses co-producing an acid fungal protease and gluco-amylase, and thereafter separating a solid phase containing acid fungal protease and a liquid phase containing glucoamylase and a glucoamylase is not a protease, but rather a amylase.

Finally, applicants submit that the use of only one protease as disclosed by Shetty does not have the advantages of the claimed invention, that is it results in further prevention or reduction of haze in a beverage.

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however, is not found nonpersuasive for the reasons previously made of record and repeated herein.

As stated previously, it is admitted that Shetty et al. do not add the two different enzymes separately after their isolation or purification, Shetty et al. do add the two enzymes inherently, by the addition of the culture of *Aspergillus niger* to the medium. In making applicants arguments, applicants have focused on that which was previously stated as being taught by Shetty et al. and applicants have not addressed that which was previously stated that the act of Shetty et al. of adding *Aspergillus niger* to the medium, as a part of the preparation of the beverage, inherently meets the limitation of adding both enzymes to the beverage. These enzymes are inherently in the *Aspergillus niger* culture that is added to the medium. Applicants are further reminded that in applicant's specification, the term "beverage" includes beverages in all stages of their preparation ( page 3, line 9).

Thus it continues that claims 17, 19, 25, 28, 34, 39, 42 and 45 are anticipated by Shetty et al.

Claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46, are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Edens et al. (US 2004/0241791 A1, published 12/2/2004).

This rejection was stated in the previous office action as it applied to previous claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46. In response to the rejection applicants have amended claims 17-25, 32-34 and 39-47 and traverse the rejection as it applies to the newly amended claims.

As previously stated, Edens et al. teach a method of enzymatically producing a protein hydrosylate intended for flavoring and nutrient enhancement of sport drinks and juice-based beverages and beer and beer mashes, comprising incubating a proline-specific endoprotease and another endoprotease with a protein substrate intended for a beverage. Edens et al. further teach said methods wherein said proline-specific carboxypeptidase is obtainable from *Xanthomonas*.

Applicants traverse this rejection on the basis that Applicants submit that their claims require that (1) the prolyl-specific endoprotease cuts a protein or peptide at places where the protein or peptide contains a prolyl residue and (2) the auxiliary enzyme is a protease.



Applicants further submit that Edens '791 clearly describes in its examples that the hydrolysates are inactivated before addition to a beverage and applicants submit several examples of such. Applicants further submit that the inactivated hydrolysate will not prevent or reduce haze therein.

Upon this basis applicants submit that this reference fails to teach or make obvious applicants claims.

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however, is not found nonpersuasive for the reasons previously made of record and repeated herein.

With regard to applicants argument that Edens et al. clearly inactivates hydrosylates prior to their addition to a beverage, applicants are reminded that as per applicants specification at page 3, line 9-line 15, applicants state that

“in the framework of this invention the term -beverage includes beverages in all stages of their preparation. Thus, a beverage is not only a beverage ready for consumption but also any composition used to prepare the beverage.”

This includes a hydolysate. Thus the addition of an enzyme to a hydroslyate meets the limitation of the claims as the addition of the enzyme to a beverage.

For this reason the rejection of claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46 is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Nagodawithana and Reed (eds.), *Enzymes in Food Processing*, 3<sup>rd</sup> Edition, Academic Press, Inc. San Diego, Chapter 16, pp 448-449, 1993) as applied to claims 17-19 , 25, 26, 28, 34, 35-37, 39, 40, 42, 43, 45, 46 above, and further in view of Edens et al. U.S. Patent No. 6,372,282 B1 published 4/16/2002).

This rejection was stated in the previous office action as it applied to previous claims 21 and 22. In response to the rejection applicants have amended claims 17-25, 32-34 and 39-47 and traverse the rejection as it applies to the newly amended claims.

As stated previously, Nagodawithana and Reed teach a method to prevent or reduce haze in a beverage, which method comprises adding a proline-specific endoprotease, as defined by applicants specification at page 3, lines 15-22, to include any endoprotease that cuts proteins or peptides near or at places where the protein or peptide contains a prolyl-residue in its chain, to the beverage, in this case beer.

Nagodawithana and Reed teach methods of reducing haze in a beverage comprising the addition of bromelin, papain and pepsin to a beverage. Nagodawithana and Reed do not teach the addition of an aspartic acid protease such as FROMASE® to the taught methods of reducing haze in a beverage.

Art Unit: 1652

As previously stated, Edens et al. U.S. Patent No. 6,372,282 B1 published 4/16/2002) teach methods of obtaining enzymatically hydrolyzed proteinaceous material for human consumption comprising the use of an exopeptidase in combination with one or more endopeptidases such as the aspartic acid protease, Fromase®.

One of skill in the art at the time of the invention would have been motivated to combine the methods taught by Nagodawithana and Reed with those taught by Edens et al. resulting in methods of hydrolyzing proteinaceous material for human consumption, comprising the combination of multiple proteases or peptidases including bromelin, papain, pepsin and fromase® to a beverage to hydrolyze proteinaceous material. The expectation of success is high due to the teachings of both Nagodawithana and Reed and Edens et al. who both teach methods of hydrolysis of proteinaceous material comprising the use of multiple proteases or peptidases. Such methods would have further resulted in predictable results given the knowledge in the field of protein hydrolysis for human consumption.

Applicants traverse this rejection on much the same basis as above, that the enzymes of Edens et al. are inactivated prior to adding the hydrosylate to another medium and that the failure of Nagodawithana and Reed to disclose the claimed invention is not remedied by Edens '282 because they do not render obvious the independent claim 17 and thus claims 21-22 are not rendered obvious.

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however, is not found nonpersuasive for the reasons previously made of record and repeated herein. As discussed above, the hydrosylate taught by

Art Unit: 1652

Edens et al. is considered a beverage given applicants definition in applicants specification as cited above. Further as claim 17 continues to be anticipated by Nagodawithana and Reed, as discussed above, it continues that claims 21 and 22 continue to be obvious over Nagodawithana and Reed and Edens et al., for the reasons discussed previously and herein.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 18, 25, 26, 28, 34, 35, 36, 37, 39, 40, 42, 43, 45, 46, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16, 31, 43, 45-61 of copending Application No. 10/450,022. Although the conflicting claims are not identical, they are not patentably distinct from

Art Unit: 1652

each other because claims 1-16, 31, 43, 45-61 of copending Application No. 10/450,022 are drawn to a method to reduce haze in a beverage comprising adding a proline-specific endoprotease comprising the amino acid sequence of SEQ ID NO: 5 to the beverage. Additionally copending Application No. 10/450,022 teaches that additional methods of the reduction of chill haze formation in beer is the addition of papain to the beer. Thus copending Application No. 10/450,022 teaches that it would be obvious to add an auxiliary enzyme such as papain as taught by 10/450,022 to the beverage in addition to a proline-specific endoprotease to reduce the haze in the beverage.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have requested that this rejection be held in abeyance until after the determination of allowable subject matter has been made

Claims 17-20, 25, 26,28, 34-37, 39, 40, 42, 43, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-17 of copending Application No. 10/433,747 Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14-17 of copending Application No. 10/433,747 are drawn to a method of enzymatically producing an protein hydrolysate from a protein substrate comprising adding a proline-specific endoprotease and one or more other endoproteases to a protein substrate, thus anticipating claims 17-20, 25, 26,28, 34-37, 39, 40, 42, 43, 45, 46 to a method of

Art Unit: 1652

reducing haze in a beverage comprising adding a praline-specific endoprotease and an auxiliary endoprotease to a beverage.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have requested that this rejection be held in abeyance until after the determination of allowable subject matter has been made

### ***Remarks***

No claim is allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rg  
11/24/2009

/Richard G Hutson/  
Primary Examiner, Art Unit 1652